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IN THE UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA

PATRICIA J. HARMON, Plaintiff, v. ACTAVIS TOTOWA LLC; ACTAVIS GROUP; MYLAN, INC.; MYLAN PHARMACEUTICALS, INC.; and UDL LABORATORIES, INC.; and DOES 1 through 10, inclusive, Defendants.	Case No. COMPLAINT AND DEMAND FOR JURY TRIAL 1. Products Liability 2. Failure to Warn 3. Breach of Express Warranty 4. Negligence 5. Fraudulent Concealment

Plaintiff, by and through her attorneys, for the Complaint and Jury Demand against Defendants, states, avers and alleges as follows:

BACKGROUND

1. This is an action for damages suffered by Plaintiff as a result of the Defendants' negligent and wrongful conduct in connection with the manufacture, development, testing, packaging, promoting, marketing, distribution, labeling, and/or sale of their drug Digitek®.

PARTIES, VENUE AND JURISDICTION

2. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332. The matter in controversy in this case exceeds the jurisdictional minimum, exclusive of interest and costs,

and the parties are citizens of different states.

3. Venue is also proper under 28 U.S.C. § 1391(a) because the acts or omissions giving rise to the Plaintiff's claim occurred in this Judicial District.

4. Venue is also proper under 28 U.S.C. § 1391(b) because the Court's jurisdiction is not founded primarily on diversity of citizenship and a substantial part of the events or omissions giving rise to the Plaintiff's claim occurred in this Judicial District.

5. Venue is also proper under 28 U.S.C. § 1391 because Defendants Actavis Totowa LLC, Actavis Group, Mylan Inc., Mylan Pharmaceuticals, Inc. and UDL Laboratories, Inc. conduct business in this District and earn substantial compensation and profits from sales of Digitek® tablets in this District.

6. Plaintiff Patricia J. Harmon at all times relevant hereto, was a resident of Placerville, California. On or about late winter or early spring of 2008, Plaintiff took defective Digitek®. As a result of taking this Digitek®, Plaintiff was hospitalized and sustained serious permanent injuries.

7. Defendant ACTAVIS GROUP (hereinafter "Defendants" or "Actavis Group"), is a foreign corporation, organized and existing under the laws of Iceland, and having a principal place of business at Reykjavikurvegur 76-78, 220 Hafnarfjordue K6 00000, Iceland.

8. Defendant ACTAVIS TOTOWA, LLC, (hereinafter "Defendants" or "Actavis") is a corporation, incorporated and existing under the laws of the State of Delaware, with its principal place of business located at 990 Riverview Drive, Totowa, New Jersey 07512. Defendant is thus a resident and citizen of Delaware and New Jersey.

9. Upon information and belief, Actavis Totowa is a subsidiary, affiliate or division of Actavis Group.

10. Defendant MYLAN, INC., (hereinafter "Defendants" or "Mylan") is a Pennsylvania corporation, registered to do business in the State of California, with its principal place of business located at 1500 Corporate Drive, Canonsburg, PA 15317.

11. Defendant, MYLAN PHARMACEUTICALS, INC., (hereinafter "Defendants" or "Mylan Pharmaceuticals") is a corporation, incorporated and existing under the laws of the State

of West Virginia, with its principal place of business located at 781 Chestnut Ridge Road, Morgantown, West Virginia, 26505.

12. Defendant UDL LABORATORIES, INC., (hereinafter "Defendants" or "UDL") is a corporation, incorporated and existing under the laws of the State of Illinois, with its principal place of business located at 1718 Northrock Court, Rockford, Illinois, 61103.

13. Upon information and belief, Mylan Pharmaceuticals and UDL are subsidiaries, affiliates or divisions of Mylan, Inc.

14. The true names and capacities, whether individual, corporate, associate or otherwise, of the defendants, Does 1 through 10, inclusive, are unknown to plaintiff, who therefore sues such defendants by such fictitious names, and plaintiff will amend this complaint to show their true names and capacities when the same have been ascertained. Plaintiff is informed and believes and thereon alleges that each of the defendants, Does 1 through 10, inclusive, is responsible under law in some manner, negligently, in warranty, strictly, or otherwise, for the events and happenings herein referred to and proximately thereby caused injuries and damages to plaintiff as herein alleged.

15. At all times relevant, Defendants and Does 1 through 10 were engaged in the business of designing, licensing, manufacturing, distributing, selling, marketing, and/or introducing into interstate commerce, either directly or indirectly through third parties or related entities, the drug Digitek®. Plaintiff alleges on information and belief that Defendants do business in California.

16. Plaintiff hereby incorporates by reference as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

FACTUAL ALLEGATIONS

17. Digitek® is one of the brand name preparations of the generic drug Digoxin (also known as Digitalis). Digoxin is a purified cardiac glycoside extracted from the foxglove plant, *Digitalis lanata*.

18. Digoxin is used to increase the strength and vigor of the heart muscle contractions and is useful in the treatment of congestive heart failure.

19. Digoxin also slows the electrical conduction between the atria and ventricles and is useful in treating abnormally rapid atrial rhythms such as atrial fibrillation, atrial flutter and atrial tachycardia.

20. Digoxin toxicity can occur from a single exposure or chronic overmedication and can cause potentially life-threatening heart rhythm disturbances, as well as nausea, vomiting, diarrhea, dizziness, confusion, loss of appetite, visual disturbances, low blood pressure, cardiac instability, irregular pulse, heart palpitations and bradycardia. At its most severe, death can result from excessive Digoxin intake.

21. The first commercially available Digoxin product approved by the Food and Drug Administration ("FDA") went on the market in 1952.

22. On April 25, 2008, the FDA announced that Actavis Totowa, manufacturer of Digitek® brand Digoxin tablets, had initiated a Class 1 nationwide recall of all strengths of Digitek® tablets (see: http://www.fda.gov/oc/po/firmrecalls/actavis04_08.html.)

23. Unbeknownst to Plaintiff, the Digitek® tablets sold to plaintiff herein were commercially released with twice the appropriate thickness, and hence, twice the approved level of active ingredient than is appropriate.

24. The Digitek® tablets were manufactured by Actavis Totowa, LLC, the United States manufacturing division of the international Actavis Group.

25. The Digitek® tablets were distributed by Mylan Pharmaceuticals, Inc., under a "Bertek" label and by UDL Laboratories, Inc. under a "UDL" label.

26. Federal regulations state: "Recall classification means the numerical designation, i.e., I, II, or III, assigned by the Food and Drug Administration to a particular product recall to indicate the relative degree of health hazard presented by the product being recalled." 21 CFR §7.3(m).

27. Pursuant to federal law, a drug is deemed to be adulterated if, "the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this chapter as to safety and has the identity and

strength, and meets the quality and purity characteristics, which it purports or is represented to possess." 21 USC §351 (a)(1)(B).

28. Pursuant to federal law, a drug is deemed to be misbranded if, among other things, its labeling is false or misleading in any particular, or if it is dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. See 21 U.S.C. §352.

29. Pursuant to federal law, the defendants are required to comply with FDA regulation of medical drugs, including FDA requirements for records and reports, in order to prohibit the introduction of medical drugs that are adulterated or misbranded, and to assure the safety and effectiveness of medical drugs. In particular, the defendants are required to record and make reports if any medical drug may have caused or contributed to death or serious injury, or if the drug has performed in a manner likely to cause or contribute to death or serious injury.

30. Pursuant to FDA regulations, the defendants, as manufacturers, packers and/or distributors of Digitek®, were required to establish and maintain records and make reports to the FDA of all serious, unexpected adverse drug experiences associated with the use of Digitek® within 15 calendar days after they became aware the event(s). Furthermore, defendants were required to promptly investigate all serious, unexpected adverse drug experiences subject to the postmarketing 15-day Alert reports and to submit followup reports within 15 calendar days of the receipt of new information or as requested by the FDA. 21 CFR §310.305(c).

31. Pursuant to FDA regulations, the defendants were required to comply with specific quality system requirements promulgated by the FDA. These requirements included a quality control unit with the "responsibility and authority to approve or reject all components, drug product containers, closures in-process materials, packaging material, labeling and drug products, and the authority to review production records to assure that no errors have occurred or, if errors have occurred, that they have been fully investigated." Furthermore, the quality control unit had the "responsibility for approving or rejecting all procedures or specifications impacting on the identity, strength, quality and purity of the drug product." Responsibilities of the quality control unit were to be in writing and followed. 21 CFR § 211.22.

32. Pursuant to FDA regulations the defendants were required to have and comply with specific written procedures for the manufacture and processing of drugs, including Digitek®, in order to "assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess." 21 CFR § 211.100.

33. Pursuant to FDA regulations, the defendants were required to calculate and verify the actual and theoretical yield of the drug at each appropriate step in the manufacturing process, to sample and test in-process materials of each batch to ensure that they conformed to manufacturing specifications, inspect and calibrate manufacturing equipment in accordance with an established written inspection program to ensure accuracy and/or precision standards were met and to ensure that equipment not meeting these standards was not used. 21 CFR §211.103, 211.110, 211.160.

34. Pursuant to FDA regulations, the defendants were required to test samples of each batch of the drug to determine satisfactory conformance to final specifications for the drug product, including the identity and strength of each active ingredient, prior to release. 21 CFR §211.165

35. With no contributory negligence on her part, Plaintiff Patricia J. Harmon ingested Digitek®, a pharmaceutical product designed, manufactured, promoted, distributed and/or sold by Defendants.

36. As a direct, proximate and legal result of the negligence, carelessness and other wrongdoing of the Defendants as described herein, Plaintiff Patricia J. Harmon suffered injury from the use of Digitek®.

37. As a direct, proximate and legal result of the negligence, carelessness, and other wrongdoing of the defendants and Does 1 through 10, as described herein, Plaintiff Patricia J. Harmon required reasonable and necessary health care, attention and services, and incurred medical, incidental and service expenses thereupon.

38. Plaintiff is informed and believes that at all times herein mentioned, the defendants, and each of them, knew of the defects of Digitek® and the probability that it would cause injury to unsuspecting users of Digitek®, including plaintiff. Defendants willfully, knowingly,

maliciously oppressively and fraudulently marketed and sold Digitek® for use by ordinary users and consumers, including plaintiff. Defendants' willful, knowing, malicious, oppressive, fraudulent and callus conduct done in conscious disregard for the legal rights, health and safety of plaintiff justifies the awarding of exemplary and punitive damages in an amount to be determined at trial.

FIRST CAUSE OF ACTION
Products Liability

39. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

40. At all times material to this action, the Defendants, and each of them, were responsible for designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling and/or selling Digitek®.

41. Defendants, and each of them, as the designers, manufacturers, makers, producers promoters, sellers, distributors, advertisers, and suppliers of Digitek® are strictly liable to plaintiff under the strict liability theory imposed by the courts of the State of California for manufacturing, designing, retailing, distributing, wholesaling, modifying, advertising promoting, etc., and placing on the market and in the flow of commerce Digitek® that was defective thereby injuring people using the product. The Digitek® was defective in that when used in a reasonably foreseeable manner according to prescription, it caused serious, permanent injuries. The Digitek® failed to contain appropriate warnings and labels of the dangers of using it, with the defendants knowing that it would be used by the public, and particularly by the plaintiff, without inspection. Said Digitek® was defective in design and unsafe for users such as plaintiff herein.

42. At all times material to this action, Defendants' Digitek® was expected to reach, and did reach, consumers in the State of California and throughout the United States without substantial change in the condition in which it was sold.

43. At all times material to this action, Digitek® was designed, developed, manufactured, tested, packaged, promoted, marketed, distributed, labeled, and/or sold by Defendants in a defective and unreasonably dangerous condition at the time it was placed in the stream of commerce in ways which include, but are not limited to, one or more of the following particulars:

a. When placed in the stream of commerce, Digitek® contained manufacturing defects which rendered the product unreasonably dangerous;

b. Digitek®'s manufacturing defects occurred while the product was in the possession and control of the Defendants;

c. Digitek® was not made in accordance with the Defendants' specifications or performance standards;

d. Digitek®'s manufacturing defects existed before it left the control of the Defendants.

44. As a direct and proximate result of the subject product's manufacturing defects, Plaintiff Harmon suffered severe and permanent physical injuries. As a further direct and proximate result of the manufacturing Defendants' wrongdoing and actions, Plaintiff Patricia J. Harmon will continue to suffer harm and economic loss.

SECOND CAUSE OF ACTION
Products Liability
Failure to Warn

45. Plaintiff hereby incorporates by reference as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows:

46. Defendants' product, Digitek®, was defective and unreasonably dangerous when the product left the possession of the Defendants in that it contained warnings insufficient to alert consumers, including Plaintiff, of the dangerous risks of over-dosage from defective Digitek® tablets and reactions associated with over-dosage of Digitek®, notwithstanding that the Defendants knew or should have known that the product was highly dangerous and created significant risks of serious bodily harm, including death to humans, if an over-dosage occurred.

47. Plaintiff ingested Digitek® and used the subject product for its intended purpose.

48. Neither Plaintiff Patricia J. Harmon, nor her physicians, could have discovered any defect in the subject product through the exercise of reasonable care.

49. The Defendants, as manufacturers and/or distributors of the subject product, are held to the level of knowledge of an expert in the field.

50. The warnings that were given by the Defendants were not accurate, clear and/or were ambiguous.

51. The warnings that were given by the Defendants failed to properly warn physicians and patients of the increased risks associated with Digitek®.

52. The warnings that were given by the Defendants failed to properly warn consumers/persons ingesting the subject product of the increased risks of injury and death from over-dosage.

53. Plaintiff reasonably relied upon the skill, superior knowledge and judgment of the Defendants.

54. The Defendants had a continuing duty to warn Plaintiff of the dangers associated with Digitek® manufactured and supplied by Defendants. Digitek® was further defective due to inadequate post-marketing warning, labeling, or instruction because, after Defendants knew or should have known of the risk of serious bodily harm and death from the ingestion of defective Digitek®, Defendants failed to provide an adequate warning to persons such as Plaintiff and/or their health care providers of the product, knowing the product could cause serious injury and death.

55. Had Plaintiff and/or her physicians received adequate warnings regarding the risks of over-dosage of Digitek®, Plaintiff would not have ingested Digitek®.

56. As a direct and proximate result of the subject product's defective and inappropriate warnings, Plaintiff Patricia J. Harmon suffered severe and permanent physical injuries. As a further direct and proximate result of the product's defective and inappropriate warnings, wrongdoing and actions of Defendants described herein, Plaintiff Patricia J. Harmon will continue to suffer loss, harm and economic loss.

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THIRD CAUSE OF ACTION
Breach of Express Warranty

57. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

58. Defendants expressly warranted that Digitek® was a safe and effective drug.

59. The Digitek® manufactured and sold by Defendants did not conform to these express representations because it caused serious injury and/or death to persons when administered in recommended dosages.

60. As a direct and proximate result of Defendants' breach of warranty, Plaintiff Patricia J. Harmon suffered severe and permanent physical injuries. As a further direct and proximate result of Defendants' breach of warranty, wrongdoing and other actions of Defendants described herein, Plaintiff Patricia J. Harmon will continue to suffer harm and economic loss.

FOURTH CAUSE OF ACTION
Negligence

61. Plaintiff hereby incorporates by reference as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows:

62. Defendants had a duty to exercise reasonable care in the design, development, formulation, manufacture, marketing, promotion, sale, labeling and/or distribution of Digitek® into the stream of commerce, including a duty to assure that the product did not pose significant risk of injury or death.

63. Defendants breached their duty of reasonable care to Patricia J. Harmon.

64. As a direct and proximate result of Defendants' negligence, Plaintiff Patricia J. Harmon suffered severe and permanent injuries. As a further direct and proximate result of Defendants' negligence, Patricia J. Harmon will continue to suffer harm and economic loss.

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FIFTH CAUSE OF ACTION
Fraudulent Concealment

65. Defendants' failure to document or follow up on the known defects in Digitek®, and concealment of known defects from the FDA, patients, Plaintiff and the medical community constitutes fraudulent concealment that equitably tolls applicable statutes of limitation.

66. Defendants are estopped from relying on the statute of limitations defense because defendants actively concealed the Digitek® defects by, among other things, suppressing reports, failing to follow through on FDA notification requirements, failing to disclose known defects to physicians. Instead of revealing the defects, defendants continued to represent Digitek® as safe for its intended use.

67. Defendants' conduct, as described in the preceding paragraphs, amounts to conduct purposely committed, which defendants must have realized was dangerous, heedless and reckless, without regard to the consequences or the rights and safety of patients.

68. Plaintiff used Digitek® in the manner for which it was intended, as prescribed by her doctor. This use has resulted in injury to Plaintiff.

69. Plaintiff was not able to discover, nor could she have discovered through the exercise of reasonable care, the defective nature of the Digitek®. Further, in no way could plaintiff have known that defendants had designed, developed, and manufactured their Digitek® in such a way as to increase the risk of harm, injury or death to persons who took Digitek®

RELIEF REQUESTED

WHEREFORE, Plaintiff prays for judgment against Defendants and relief as follows in amounts to be determined at trial:

1. Compensatory damages in excess of the jurisdictional amount, including, but not limited to pain, suffering, emotional distress, loss of enjoyment of life, and other non-economic damages in an amount to be determined at trial of this action;
2. Compensatory damages in excess of the jurisdictional amount, including but not limited to medical expenses, lost future income, loss of earning capacity, out-of-

pocket expenses, and other economic damages in an amount to be determined at trial of this action;

3. Pre- and post-judgment interest;
4. Attorneys' fees, expenses, and costs of this action as allowed by law;
5. Punitive/Exemplary damages; and
6. Such further relief as this Court deems necessary, just and proper.

JURY TRIAL DEMANDED

Plaintiff demands a trial by jury on all issues.

Dated: July 17, 2008

KERSHAW, CUTTER & RATINOFF, LLP

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